PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|---|---|---|---|
| Applicants: | Nargund et al. | | |
| Serial No.: | 10/730,704 | Case No.: 21151 | Art Unit: 1614 |
| Filed: | December 8, 2003 | | Examiner: Phyllis G. Spivack |
| For: | COMBINATION THERAPY FOR THE TREATMENT OF OBESITY | | |

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This is in response to the Restriction Requirement of June 2, 2006, for which a response is due by July 2, 2006. The Examiner is respectfully requested to consider the accompanying amendments and remarks. Any additional fees associated with this Response may be charged to Merck Deposit Account No. 13-2755.

**Remarks** begin on page 2 of this paper.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By _____ Date 6/27/2006

RESTRICTION REQUIREMENT UNDER 35 U.S.C. 121

In addition to the restriction requirement of February 13, 2006, the Examiner has stated that further restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Methods and Compositions comprising two active agents in the five categories for which species were elected in the Response of March 10, 2006, in a method of treating diabetes; elevated plasma insulin concentrations; insulin resistance.

II. Methods and Compositions comprising two active agents in the five categories for which species were elected in the Response of March 10, 2006, in a method of treating obesity that is unrelated to diabetes; overeating; bulima.

III. Methods and Compositions comprising two active agents in the five categories for which species were elected in the Response of March 10, 2006, in a method of treating hypertension.

IV. Methods and Compositions comprising two active agents in the five categories for which species were elected in the Response of March 10, 2006, in a method of treating dyslipidemia, hyperlipidemia.

V. Methods and Compositions comprising two active agents in the five categories for which species were elected in the Response of March 10, 2006, in a method of treating endometrial, breast, prostate and colon cancer; acute lymphoblastic leukemia.

VI. Methods and Compositions comprising two active agents in the five categories for which species were elected in the Response of March 10, 2006, in a method of treating osteoarthritis.

VII. Methods and Compositions comprising two active agents in the five categories for which species were elected in the Response of March 10, 2006, in a method of treating sleep apnea.

VIII. Methods and Compositions comprising two active agents in the five categories for which species were elected in the Response of March 10, 2006, in a method of treating cholelithiasis.

IX. Methods and Compositions comprising two active agents in the five categories for which species were elected in the Response of March 10, 2006, in a method of treating coronary heart disease, abnormal heart rhythms, heart arrhythmias, myocardial infarction.

X. Methods and Compositions comprising two active agents in the five categories for which species were elected in the Response of March 10, 2006, in a method of treating polycystic ovary disease, GH-deficient subjects, metabolic syndrome, normal variant short stature, Frohlich's syndrome, Prader-Willi syndrome.

XI. Methods and Compositions comprising two active agents in the five categories for which species were elected in the Response of March 10, 2006, in a method of treating craniopharyngioma, Turner syndrome.

Applicants hereby provisionally elect to prosecute the invention and claims of Group II, directed to methods and compositions comprising two active agents in the five categories for which species were elected in the Response of March 10, 2006, in a method of treating obesity that is unrelated to diabetes; overeating; bulima, with traverse.

For proper restriction, two criteria must be met: (1) the inventions must be independent or distinct as claimed; and (2) there must be a serious burden on the Examiner if restriction is not required. MPEP § 803. Applicants submit that there is no serious burden in combining the restricted groups into one search. A search of the compositions of the two species and methods of using them would also provide search results relating to the indications that the compositions are useful to treat. Consequently, would be more efficient for the Examiner to search all of the indications together for the elected compositions.

Applicants further request that the Examiner not limit the obesity indication in Group II to obesity unrelated to diabetes, since many diabetics are obese. Applicants request that Group II include obesity in any patient group.

In light of the above reasons, Applicants respectfully request that the requirement for restriction between Groups I-XI be withdrawn. In the event that the restriction requirement is made final, Applicants elect Group II, as indicated above, holding Groups I and III-XI in abeyance for further prosecution in a divisional application.

Applicants believe that all of the objections and rejections have been overcome by amendment and/or argument, and therefore earnestly solicit an early Notice of Allowance.

Respectfully submitted,

By Baerbel R. Brown

Baerbel R. Brown, Reg. No. 47,449
Attorney for Applicants
MERCK & CO., Inc.
P.O. Box 2000
Rahway, NJ 07065-0907
Tel.: (732)594-0672

June 27, 2006